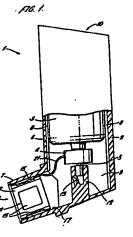
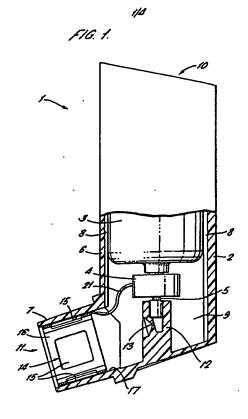
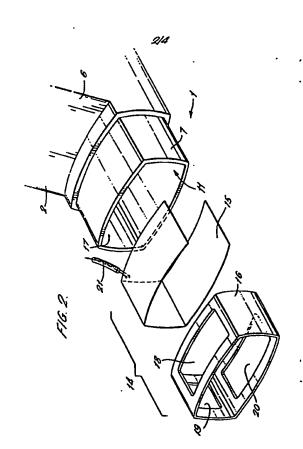
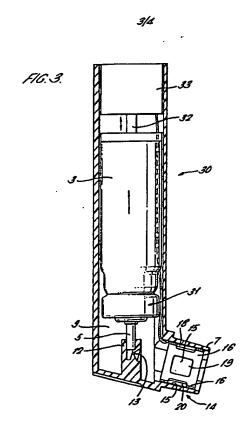
UK Patent Application (m) GB (1) 2 266 466 (A) A (4) Date of A publication (L) L (10)

(31) SIT CL¹ ABIN 1500 (20) Date of Eling COLAN.1923 UK CA (Edition L) AST 198 TED TIGG THAT PAR ROC







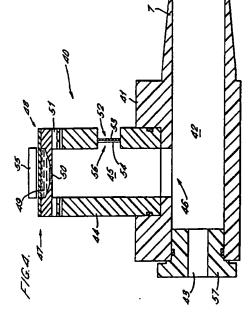


This invention relates to inhalation apparatus for dispensing inhaled substances and in particular but not exclusively to dispensing of medicinal products in serosol form from a pressurised dispensing container.

It is known to provide a sensor in an inhelation apparatus to detect inhalation by a user in order to synchronise with inhalation the release into the inhaled air flow of a substance to be inheled. It is for example important in the edministration of aerosol products for the relief of asthma that the tining of the dispensing operation should be carefully controlled to ensure maximum deposition of the substance in the user's lungs.

It is known from WC87/04354 to provide an electrically operated dispensing means responsive to a signal generated by a sensor which is responsive to the flow of air through a pessageway. A hinged flap cooperates with a reed contact to make electrical contact and generate an actuating signal for the dispensing means.

According to the present invention there is
disclosed inhalation apparatus for dispensing inhaled
substances comprising a housing defining a passageway
for inhaled air, a dispensing means operable in
response to an electrical actuating signal to
dispense into the passageway a substance to be
inhaled, and a sensor operable to produce the
actuation signal in response to inhalation wherein
the sensor comprises a membrane of piesoelectric
material and support means supporting the membrane
relative to the housing at a location such that the
sensor flexes in response to a change of air
pressure in the passageway to thereby generate the



actuation signal.

An advantage of such apparatus is that it provides a sensor of simple construction and which is relatively easy to assemble with the housing. A further edvantage is that the sensor generates an actuation signal by piezoelectric action which does not require the sensor to be energised from an external electrical source.

- 2 -

Preferably the numbrane comprises a flexible polymeric piezoelectric material such as polyvinylidene fluorida (PVDF).

Conveniently the support means comprises a support member cooperating with the bousing to clamp a clamped portion of the membrane in fixed relationship with the bousing, the clamped portion being peripharal to at least one unclamped portion which is flexible in response to pressure change in the passageway.

Preferably the numbrane overlays a portion of a side wall defining the passageway.

The number may alternatively be nounted on a resilient diaphragm for flexure in unison with the diaphragm, the diaphragm being located such that one side of the diaphragm is exposed to ambient air pressure and the other side of the diaphragm is exposed to eir within the passageway.

Preferred'embodinemts of the present invantion will now be described by way of example only and with reference to the accompanying drawings of which:-

30 Figure 1 is a part sectioned elevation of an inhalation apparatus;

Figure 2 is an exploded perspective view of the apparatus of Figure 1:

Figure 3 is a part sectioned elevation of an 15 alternative apparatus; and

Figure 4 is a sectioned elevation of a further

alternative apparatus.

70

Apparatus 1 of Figure 1 comprises a generally tubular housing 2 receiving a cylindrical pressurised dispensing container 3. The container 3 has an electrically operated outlet valve 4 which is operable to release a metared dose of a medicinal product through a valve stem 5 in response to an electrical actuating eignal.

- 3 -

The housing 2 consists of a main tubular portion 6 which receives the container 3 and a mouthpiece 7 projecting laterally from the lower end of the main tubular portion. The main tubular portion 6 includes circumferentially spaced ribs 8 which project invardly so as to space the container 3 from the housing 2 to allow air to flow around the container 3. An air passageway 9 is defined by the housing 2 and extends from an open end 10 of the housing, through the main tubular portion 6 and through the mouthpiece 7 to an outlet 11.

The valve stem 5 is received in a nozzle fitting 12 having a nozzle opening 13 arranged to direct an aerosol apray from discharge through the valve in a direction towards the outlet 11.

A sensor 14 is located in the nouthpiece 7 and comprises a piezoelectric membrane 15 which is held by a support member 16 so as to normally lie in contact with an annular side wall portion 17 of the mouthpiece 7.

As shown more clearly in Figure 2 the support
number 16 is generally tubular in shape and fits
smugly within the nouthpiece 7. The support number
16 is provided with cut-outs 18, 19 and 20 through
which corresponding unclamped portions of the
number 15 are exposed, each exposed portion of the
number 15 are exposed, each exposed portion of the
perhrane 15 are exposed, each exposed portion of the
perhrane being surrounded by an annular clauped
portion which is overleid by the support number 16

and clamped in contact with the side wall portion 17.

The membrane 15 is a film of PVD? (polyvinylidene fluoride) naterial upon which are formed sensor electrodes (not shown) in known manner to provide an electrical output signal responsive to flexure of the film.

An output lead 21 connects the membrane to the valve 4 which includes suitable circuitry to actuate the valve in response to an actuating signal.

In use a user inhales air through the
nouthplace 7 resulting in a drop of sir pressure
within the mouthplace. Air flows through the
housing 2 from the open and 10 to the outlet 11.
The presence of the container 3 in the main tubular
portion 6 results in the passageway 9 being
constricted adjacent to the open and 10 which tends
to anhance the drop in pressure of the air within the
mouthplace 7.

In response to the drop of air pressure within

the mouthpiece 7 the numbrane 15 flexes such that
exposed portions of the membrane 15 how into the
cut-cuts 18, 19 and 20 and this flexure of the
membrane results in an actuating signal being
generated by plescelectric action in the membrane and

transmitted via cutput lead 21 to the valve 4.

The valve 4 is actuated by the actuating signal and releases a measured dose of medicament into the mossle fitting 12 from which it is dispensed as an aerosol spray through the mossle opening 13 into the mouthplace 7 so as to be entrained in the air flow and hence inhaled by the user.

When the inhalation ceases the membrane relaxes to its rest position in which it lies in contact with the side wall portion 17. During this relaxation of the membrane a signal of opposite polarity is gumerated by the membrane. The circuitry of the

- 6 -

7 communicating via a tubular duct 42 with an inlet opening 43 arranged such that the inlet opening and mouthpiece 7 are at opposite ends of the tubular duct.

The housing 41 includes a side arm 44 defining 5 a second duct 45 communicating with the first duct 42 at a T-junction 46.

The side arm 44 has an outer end 47 at which is located a piescelectric atomiser 48 of a type in which liquid from a liquid reservoir 49 is dispensed through a perforate membrane 50 in response to high frequency vibration of the membrane 50 by a piescelectric element 51.

A side port 52 is formed in the side arm 44 intermediate the T-junction 46 and the atomiser 48 and the side port is closed by an elastomaric disphragm 53. A piesecelectric membrane 54 of PVDF material is bonded to the disphragm 53 so as to flex in unison with the disphragm. The membrane 54 is provided with smitable electrodes (not shown) for semsing piesoslectrically induced voltages resulting from flowure of the membrane and which are commerted to an electronic control unit 55 which is operable to actuate the stomiser 48. The membrane 54 and disphragm 53 constitute a sensor 56 which is responsive to pressure change in the second duct 45.

The inlet opening 43 is defined by an animalar formation 57 which provides a constriction to the flow of air through the dust 42.

In use a user inhales air through the
nouthplece 7 and an air flow is established through
the duct 42 from the restricted inlet opening 43. A
pressure drop established within the duct 42 is
communicated to the second duct 45 resulting in
inward flaumre of the disphragm 53 and with it the

Description of the second duct 45 resulting in
invard flaumre of the disphragm 53 and with it the
piezoelectric estion an actuating signal transmitted

valve 4 is arranged to not respond to a signal of this reverse polarity.

An alternative apparatus 30 is shown in Figure 3 and is described using corresponding reference numerals to those of Figure 1 where appropriate for corresponding elements.

The alternative epparatus 30 has a pressurised dispensing container 3 having a conventional mechanical valve 31 which is actuated by depression of a valve stem 5 relative to the container. The valve stem 5 is received in a fixed nossle fitting 12 and the container is moved towards and away from the nossle fitting by a solenoid operated plunger 32. The plunger 12 is driven by an electrical actuator 33 which is connected to a sensor 14 which corresponds to the sensor 14 of the apparatus of Figures 1 and 2. Sensor 14 is similarly located in a mouthpiece 7 of housing 2.

In use a user inhales air through the mouthpiece 7 and air is drawn through a passageway 9 defined by housing 3. Air pressure within the mouthpiece is decreased by the inhalation so that the membrane 15 flaves so as to bow into the cut-outs 18, 19, and 20 of the support number 16. An actuating signal is transmitted to the actuator 33 resulting in the plunger 32 being moved by solemoid action so as to translate the container 3 towards the norsele fitting 12. The valve 31 operates to release a medicinal product through the stem 5 which is

opening 13.

A further alternative apparatus 40 is shown in Figure 4 and will be described using corresponding reference numerals to those of previous Figures where appropriate for corresponding elements.

atomised and injected into the air flow by the nozzle

Apparatus 40 has a housing 41 with a mouthpiece

- 7

to the control unit 55 resulting in the atomiser 48 being actuated. A mist of liquid is dispensed from the reservoir 49 through the perforate membrane 50 into the second duct 45 and is drawn into the duct 42 from whence it is inhaled through the nouthplece 7.

On completion of inhalation the pressure within the ducts 42 and 45 is restored to atmospheric pressure and the disphregs 53 relaxes to its rest position. During this relaxation a signal of opposite polarity is generated by the sensor 56. The control unit 55 is arranged not to respond to

reverse polarity signals.

15

20

25

30

35

CLADIS:

- Inhalation apparatus for dispensing inhaled substances comprising a bousing defining a passegaway for inhaled air, a dispensing means operable in rumponse to an electrical actuating signal to dispense into the passegaway a substance to be inhaled, and a sensor operable to produce the actuation signal in response to inhalation wherein the sensor comprises a membrane of piezoelectric material and support means supporting the membrane relative to the housing at a location such that the membrane flaxes in response to a change of air pressure in the passageway to thereby generate the actuation signal.
 - Inhalation apparatus as claimed in claim 1 wherein the membrane comprises a polymeric pieroelectric material.
 - Inhalation apparetus as claimed in claim 2 wherein the piezoelectric material is polyvinylidene fluoride.
- 4. Inhalation apparatus as claimed in any preceding claim wherein the support means comprises a support member cooperating with the housing to clamp a clamped portion of the membrane in fixed relationship with the housing, the clamped portion being peripheral to at least one unclamped portion which is flavible in response to pressure change in the passageway.
- Inhalation apparatus as claimed in claim 4
 wherein the manhrane overlays a portion of a side wall defining the passageway.

Section 17 (The Search Report)			Application number						
			Search Examiner J A WALLIS Date of Search						
					(i) UK Patent Office			22 MAY 1992	
					(22 RAI	4994
Documents cons	idered relevant following a search in respect of claims	ALL							
Catagory (see over)	identity of document and relevant passages			Relevant to claim(s)					
	коле .								
•									
			Ì						

- 6. Inhelation apparatus as claimed in any of claims 1 to 4 wherein the member is mounted on a resilient disphragm for flavore in unison with the 5 disphragm, the disphragm being located such that one side of the disphragm is exposed to ambient air pressure and the other side of the disphragm is exposed to air within the passageray.
- 7. Inhalation apparatus substantially as hereinbefore described with reference to and as shown in any of the accompanying drawings.

25

35

A: Document indicating technological backgroundler state of the art.

Categories of documents

Categories of documen

Databoses: The UX Pazzer Office database computers obscided collections of GR, EP, WO and US pazzer specifications as outlined periodically in the Official Journal Pazzeria. The on-time databases considered for earth or at loss based periodically in the Official Journal (Pazzeria).